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EXAMINER	
CLARK, AMY LYNN	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,915	YANO ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 February 2007 has been entered.

Acknowledgment is made of the receipt and entry of the amendment filed on 6 February 2007 with the cancellation of Claims 1-3, and newly added Claim 5.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Clams 4 and 5 are currently pending.

Claims 4 and 5 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide prior support or antecedent basis for the language "one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on

the total weight of the composition" and "skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition" and failing to comply with the written description requirement. The claim as set forth in the amendment filed 6 February 2007 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In the instant case, the original Claim 4 did not disclose the exact total amount of the mixture of ingredients, wherein Applicant claimed, as Claim 4, "A method for inhibiting aging, comprising the step of applying the anti-aging preparation according to claim 2 onto the skin". Since Claim 5 is new, the amount of the mixture of ingredients was not previously disclosed in this Claim or any previously pending claims. In amended Claim 4, Applicant claims, "A method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract" and in newly submitted Claim 5, Applicant claims, "The method of claim 4, wherein the one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition", thereby introducing a specific volume of a mixture of crude drugs, wherein it appears that Applicant is claiming that all of the drugs when combined are present in a total amount of 0.0001 to 20.0% by mass

as a dry substance based on the total weight of the composition and that Applicant is claiming that all of the drugs when combined are present in a total amount of 0.0001 to 10.0% by mass as a dry substance based on the total weight of the composition, which is considered to be new matter. Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept for a composition comprising 1 cup of white rum and two or three teaspoons of rosemary added to the volume of white rum. There is only one exemplified composition comprising the claim-designated ingredients having the functional effect for treating pimples and acne. Page 9, lines 2-7 (paragraph 0033 of the PreGrant Publication) of the specification discloses, "The formulating amount of the agent having angiogenesis inhibitory activity in the angiogenesis inhibiting preparation or the anti-aging preparation according to the present invention is 0.0001 to 20.0% by mass, preferably 0.0001 to 10.0% by mass, as a dry substance based on the total amount of the composition". This is not sufficient support for the new genus: "A method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract", in Claim 4 and in newly submitted Claim 5, "The method of claim 4, wherein the one or a plurality of crude drugs

is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition". This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.O1(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been

considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The claims are drawn to a method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract and one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition.

Breadth of the Claims: The claims are broad in that any extract of da zao, ginseng, roman chamomile, chlorella, coicis semen and silk on their own or in combination, present in an amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition and in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition may be administered to inhibit any type of aging in a patient. For example, Applicant could be claiming that these drugs could stop people from getting older, however, this is impossible, since there is no evidence that anything can stop time or people from getting older (See 112 1st paragraph/ 101 utility rejection below). The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes an angiogenesis inhibiting preparation, comprising a given

agent, which exhibits TSP-I induction activity and inhibits angiogenesis upon induction of the death of vascular endothelial cells, and an anti-aging preparation, particularly an anti-aging external preparation for skin, characterized by comprising, as an active component a given agent, and which exhibits an anti-aging action, particularly an anti-photoaging action, by virtue of an angiogenesis inhibitory activity (See page 1, "Technical Field"), an in vitro method of preparing a cell strain by stably transfecting HaCat cells with a DNA construct comprising a luciferase-coding gene as a reporter gene ligated to the downstream of a TSP-I promoter, was provided, wherein the cell strains were measured for luciferase activity with Luciferase Assay System (Promega) and the luciferase activity was regarded as TSP-I promoter activity. The specification alleges the experimented various plant extracts, some extracts including da zao extract (I), ginseng extract (2), roman chamomile extract (3), chlorella extract (4), celery extract (5), parsley extract (6), coicis semen extract (7), and silk extract (8) (all extracts being available from Ichimaru Pharcos Co., Ltd.) exhibited effective TSP-1 promoter activity, however, the specification does not describe a method of measuring these effects. The results of experiments using these crude drugs are shown in Fig. 1. The specification further describes a method of secondary screening in vivo study of an apotosis inducer, wherein the agent (one thousandth) in the primary screening was added to vascular endothelial cell HMVEC (Sanko Junyaku Co., Ltd.) which had been cultured on a chamber slide until about 70% confluent, followed by culture for 24 hr to examine cell death induction of vascular endothelial cells, the detection of the cell death was carried out by using an ApopTag Plus Fluorescein In Situ Apoptosis Detection Kit, and

calculation of the cell death induction ratio was carried out by calculating the proportion of the number of the died cells in the group to which the agent had been added, relative to the that of the control group, the calculation was carried out by a process comprising taking images for three sites in each slide of the group in which the agent had been added and the control group by a digital camera, and then calculating the proportion of the number of cell death-signals to the number of nuclei in each image (%), and the results revealed that, among the tested various plant extracts, da zao extract (I), ginseng extract (2), roman chamomile extract (3), chlorella extract (4), celery extract (5), parsley extract (6), coicis semen extract (7), and silk extract (8) effectively induce apotosis of vascular endothelial cells. The disclosure further describes that the results of the experiment using these crude drugs are shown in Fig. 2. For comparison, the results of an experiment in which only the medium (in the drawing, right bar: one ten thousandth, left bar: one thousandth), DMSO (in the drawing, right bar: one ten thousandth, left bar: one thousandth), or TSP-I (one thousandth) (Haematologic Technologies, Inc.) was allowed to act instead of the candidate agents are also shown and that the results of the above two types of screening show that da zao extract, ginseng extract, roman chamomile extract, chlorella extract, celery extract, parsley extract, coicis semen extract, and silk extract are effective for inducing TSP-I and inducing apotosis of vascular endothelial cells (See Example 1 and Example 2 on pages 10-12). Please note that nowhere in the specification does Applicant provide examples of compositions of more than one extract in a composition providing any effect. Furthermore, please note that Applicant does not describe the extracts of each

individual crude drug (da zao, ginseng, roman chamomile, chlorella, coicis semen and silk) in the examples provided.

The specification envisions that the that some crude drugs, such as da zao extract, ginseng extract, roman chamomile extract, chlorella extract, celery extract, parsley extract, coicis semen extract, and silk extract, can effectively prevent or inhibit aging and will have utility in humans in inhibiting aging.

However, no working examples are provided with regard to a method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract and one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition. Furthermore, no working examples are provided that demonstrate the efficacy of a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract and one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition, wherein the composition inhibits aging.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, Wang et al. (U, Zhong Xi Yi Jie He Za Zhi. 1991; 11(2): 159-161, Abstract only) teaches that aqueous extracts of *Ziziphus jujuba* (da zao) have antioxidant activity *in vivo* and *in vitro* in mouse liver homogenate. Morisaki et al. (V, Br. J. Pharmacol. 1995; 115(7): 1188-1193, Abstract only) teaches an *in vitro* study on the effects of saponin from Ginseng Radix rubra on angiogenesis (tube formation) and its key steps (protease secretion, proliferation and migration) in human umbilical vein endothelial cells (HUVEC), which were examined to elucidate the mechanism of the tissue repairing effects of Ginseng Radix rubra and an study of a wound healing model was performed on skin of diabetic rats. Morisaki further teaches that saponins at 10-100 micrograms ml-1 significantly stimulated tube formation by HUVEC in a dose-dependent manner and that saponin in a similar concentration-range increased the secretion of tPA from HUVEC as estimated by immunoreactivity and enzyme activity; however, on the other hand, PAI-1 immunoreactivity was slightly increased at 10 micrograms ml-1 of saponin, but then was significantly decreased at 50 and 100 micrograms ml-1. Morisaki further teaches that cell proliferation was only slightly enhanced by 1-100 micrograms ml-1 of saponin, but migration was significantly enhanced by 10-100 micrograms ml-1 in a dose-dependent manner and that saponins increased wound healing. Rucker et al. (W, Arch Pharm (Weinheim). 1989; 322(11): 821-826, Abstract only) teaches that the ethanol extract of Anthemis nobilis (Roman chamomile) show a medium antibacterial activity. Yasukawa et al. (X, Biol. Pharm. Bull. 1996; 19(4): 573-576) teaches a methanol extract of

chlorella vulgaris induced inflammation in mice, as did the hexane soluble fraction obtained from the methanol fraction. Yasukawa further teaches that ergosterol peroxide, obtained from the extracts of chlorella vulgaris inhibited the tumor-promoting effect of TPA (12-0-tetradecanoylphorbol-13-acetate). http://web.archive.org/web/*/http://www.dragonherbs.com/programs/programs.asp?program=5 (U1) teaches that coix is a very nourishing herb which has special effects on the skin and that it is famous for its ability to remove blemishes, including aging spots. Zaoming et al. (V1, J. Investig. Allergol. Clin. Immunol. 1996; 6(4): 237-241, Abstract only) teaches that mulberry silk extracts contain allergens and some of the allergens have been characterized. Zaoming teaches that there is a discrepancy between *in vivo* and *in vitro* results of the study. Please note that with regards to the teachings above, it is important to note that most animals are poor predictors of human diseases, as taught by Kaufman (W1, Perspectives on Medical Research. 4; 1993).

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract and one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition. The Office further notes that while the specification discloses that the claim-designated

methods and claim designated compositions will have utility in humans in inhibiting aging, nowhere in the specification or in the limitations does Applicant direct the claimed subject matter to the administration of compositions comprising a composition comprising one or a plurality of crude drugs selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract, nor does Applicant disclose applying compositions comprising the claimed amounts to any subject.

It should be noted that at the time of filing of the present application, the art of medicine did not recognize the administration of compositions comprising one or a plurality of crude drugs selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract for inhibition of aging comprising the step of administering compositions comprising one or a plurality of crude drugs selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract, wherein said compositions comprising one or a plurality of crude drugs selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract inhibit aging in humans.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to use any compositions comprising one or a plurality of crude drugs selected from the group consisting of da zao extract,

ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract in the inhibition of aging in humans. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify compositions comprising one or a plurality of crude drugs selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 4 and 5 are not considered to be fully enabled by the instant specification.

Claims 4 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant claims "A method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract", as claim 4 and "The method of claim 4, wherein the one or a plurality of crude drugs is

present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition", as claim 5. Applicant is claiming that applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract will inhibit aging. At the present time, it has not been shown or proven that any cosmetic, topically applied composition or nutritional supplement is capable of inhibiting aging, particularly since it appears that Applicant is claiming that aging relates to any type of aging, and there is no evidence that time may be stopped or that anything can stop people from getting older, nor is there any evidence that aging of skin or any other body part may be inhibited (please note that inhibited means stopped and this infers that aging would be all together halted by application of this composition). Moreover, if aging could be inhibited, then people would not get older. However, all people continue to age. Thereforea composition comprising one or a plurality of crude drugs selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract is not capable of inhibiting aging.

Claims 4 and 5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 5 and 6 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter. Although the use of common names or traditional/ethanopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical as noted in this application. The common name or traditional/ethanopharmacological name may have several different Latin names referring to various genus-species of the plant and it is unclear as to which genus and species Applicant is referring. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Applicant may overcome the rejection by placing the genus-species name of "da zao", "ginseng", "roman chamomile", "chlorella", "coicis semen", and "silk" in parentheses after the terms"da zao", "ginseng", "roman chamomile", "chlorella", "coicis semen", and "silk". Please make sure to write the Latin name in the proper format, wherein the first word is capitalized, the second word is lowercase and the entire name is italicized.

The metes and bounds of Claim 4 are rendered uncertain by the phrase "a

method of inhibiting aging", "a zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract". First of all, what does Applicant mean by "inhibiting aging"? Please see the 112 1st paragraph rejections above and the 35 USC 101 rejection below. Secondly, what type of extract of cinnamon and creatine Applicant is referring to. For example, Applicant could be claiming an aqueous/organic extract or Applicant could be claiming a specific compound (or compounds) extracted from each ingredient. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant claims "A method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract", as claim 4 and "The method of claim 4, wherein the one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the

total weight of the composition", as claim 5. Applicant is claiming that applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract will inhibit aging. At the present time, it has not been shown or proven that any cosmetic, topically applied composition or nutritional supplement is capable of inhibiting aging, particularly since it appears that Applicant is claiming that aging relates to any type of aging, and there is no evidence that time may be stopped or that anything can stop people from getting older, nor is there any evidence that aging of skin or any other body part may be inhibited (please note that inhibited means stopped and this infers that aging would be all together halted by application of this composition). Moreover, if aging could be inhibited, then people would not get older. However, all people continue to age. Thereforea composition comprising one or a plurality of crude drugs selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract is not capable of inhibiting aging.

Claims 4 and 5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

Claim Rejections - 35 USC § 102

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 6 February 2007, with respect to the rejection(s) of claim 4 under 35 U.S.C. 102(b) as being anticipated by Tominaga (A*) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection of claim 4 and newly presented claim 5 is made under 35 U.S.C. 102(b) as being anticipated by Kitada et al. (N, JP 10-017459 A, Translation provided herein), as being anticipated by Ito et al. (O, JP 08-109122 A, Translation provided herein)), and as being anticipated by Matsui et al. (P, JP 05-032537 A, Translation provided herein). Claims 4 and 5 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Tominaga (A*), in view of Kitada et al. (N, JP 10-017459 A, Translation provided herein), Ito et al. (O, JP 08-109122 A, Translation provided herein), Fugitani et al. (Q, JP 11-228437 A, Translation provided herein), and Matsui et al. (P, JP 05-032537 A, Translation provided herein).

Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitada et al. (N, JP 10-017459 A, Translation provided herein).

Kitada teaches a method of improving dullness from skin aging comprising administering a composition comprising one or more ununiformity improvement enhancement agents of the suitable skin concerned to carry out improvement prevention of the dullness resulting from the ununiformity improvement agent of the skin, aging, etc, wherein the heterogeneity improvement agent of the skin the essences, which is the processed product and/or the solvent extract or its solvent-removed product

of the plant, and their fractions of *Panax ginseng* Meyer and *Zizyphus jujuba* Mill. Kitada further teaches that the heterogeneity comprises 0.001-10% of the weight of the composition (See Abstract, paragraphs 0001, 0005-0007, 0017, 0026 and Example, paragraphs 0027-0037, particularly paragraph 0037).

Therefore, the reference anticipates the claimed subject matter.

Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al. (O, JP 08-109122 A, Translation provided herein).

Ito teaches a method of improving the skin by inhibiting wrinkles comprising the step of applying a composition comprising an extract of Anthemis nobilis L in an amount of 0.01-10 wt% (See Abstract and paragraphs 0006, 0011 and 0023-0037).

Therefore, the reference anticipates the claimed subject matter.

Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsui et al. (P, JP 05-032537 A, Translation provided herein).

Matsui teaches a method of improving the skin by inhibiting wrinkles comprising the step of applying a composition comprising 0.5-4wt.% silk fiber to skin (See Abstract and paragraphs 0018-0033).

Therefore, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tominaga (A*), in view of Kitada et al. (N, JP 10-017459 A, Translation provided herein), Ito et al. (O, JP 08-109122 A, Translation provided herein), Fugitani et al. (Q, JP 11-228437 A, Translation provided herein), and Matsui et al. (P, JP 05-032537 A, Translation provided herein).

Tominaga teaches a method of inhibiting cutaneous aging comprising applying an effective amount of an anti-aging composition to skin comprising one or two aminoethyl compounds and further comprising ginseng extract and coicis semen (*Coix lachryma-jobi*) extract (See claim 1 and column 6, lines 63-65), which reads on a

method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of drugs selected from the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract and silk extract.

The teachings of Kitada are set forth above and applied as before.

The teachings of Ito are set forth above and applied as before.

Fugitani teaches a method of inhibiting aging in skin comprising applying a composition comprising extract of chlorella (See abstract and paragraphs 0008-0012 and 0030-0046).

The teachings of Matsui are set forth above and applied as before.

The teachings of Tominaga, Kitada, Ito, Fugitani and Matsui are set forth above and applied as before. Tominaga does not teach a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, nor that the one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the amounts of each crude drug in a composition administered to provide a composition used in the method of inhibiting aging, comprising the step of applying onto the skin a composition comprising one or a plurality of crude drugs, present in the amount of 0.0001 to 20.0 by mass % as a dry substance based on the total weight of the composition, selected from

the group consisting of da zao extract, ginseng extract, roman chamomile extract, chlorella extract, coicis semen extract, and silk extract, and wherein the one or a plurality of crude drugs is present in the amount of 0.0001 to 10.0 by mass % as a dry substance based on the total weight of the composition because at the time the invention was made, Tominaga teaches a method of inhibiting cutaneous aging comprising applying an effective amount of an anti-aging composition to skin comprising one or two aminoethyl compounds and further comprising ginseng extract and coicis semen (*Coix lachryma-jobi*) extract was known in the art, as clearly taught by Tominaga, as was a method of improving dullness from skin aging comprising administering a composition comprising one or more ununiformity improvement enhancement agents of the suitable skin concerned to carry out improvement prevention of the dullness resulting from the ununiformity improvement agent of the skin, aging, etc, wherein the heterogeneity improvement agent of the skin the essences, which is the processed product and/or the solvent extract or its solvent-removed product of the plant, and their fractions of *Panax ginseng* Meyer and *Zizyphus jujuba* Mill. And that the heterogeneity comprises 0.001-10% of the weight of the composition, as clearly taught by Kitada, as was a method of improving the skin by inhibiting wrinkles comprising the step of applying a composition comprising an extract of Anthemis nobilis L in an amount of 0.01-10 wt%, as clearly taught by Ito, as was a method of activating cell stimulate aging prevention and improvement of surface deterioration, wrinkle formation comprising administering a composition comprising an extract of chlorella, as clearly taught by Fujitani (please note that although Fujitani does not expressly teach

the amount of chlorella extract claimed by Applicant, Fujitani teaches that the extract has the same effect as the extract claimed by Applicant, and therefore, it would have been a matter of routine optimization to adjust the amount of extract used for the purposes Applicant is claiming- see below), as was a method of improving the skin by inhibiting wrinkles comprising the step of applying a composition comprising 0.5-4wt.% silk fiber to skin, as clearly taught by Matsui.

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that extracts of da zao, ginseng, Roman chamomile, chlorella, coicis semen and silk extract are effective ingredients in compositions for treating signs of aging in skin, it would have been obvious to combine these plants with the expectation that such a combination would be effective in skin care compositions and for treating aging skin. Thus, combining them flows logically from their having been individually taught in prior art.

Furthermore, it would have been obvious to one of ordinary skill in the art and would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the composition used in the method taught by Tominaga by adjusting the amounts of a beneficial extract to provide the instantly

claimed invention because at the time the invention was made, a method for inhibiting aging in skin by applying extracts of da zao, ginseng, Roman chamomile, chlorella, coicis semen and silk extract, as clearly taught above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MICHELE FLOOD
PRIMARY EXAMINER

Amy L. Clark
March 31, 2007

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